

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, ET AL. *ex*  
*rel.* CATHERINE A. BROWN and  
BERNARD G. VEZEAU,

Plaintiffs,

v.

PFIZER INC,

Defendant.

Civil Action No.: 05-6795

Hon. R. Barclay Surrick

**RESPONSE TO RELATORS' SIXTH NOTICE OF SUPPLEMENTAL AUTHORITY**

Defendant Pfizer Inc ("Pfizer") respectfully submits this memorandum in response to the Notice of Supplemental Authority (ECF No. 92, Oct. 21, 2015) recently filed by Relators Catherine Brown and Bernard Vezeau ("Relators"), and in support of Pfizer's pending motion to dismiss (ECF No. 42, Apr. 9, 2012).

**BACKGROUND**

Pfizer has moved to dismiss Relators' amended complaint because, among other things, Relators have failed to plead a cause of action under the False Claims Act ("FCA") based on Pfizer's alleged off-label promotion of Vfend. (*See* Def.'s Mem. at 14-25.) In a case like this one, "the alleged FCA violation arises – not from the unlawful off-label marketing activity itself – but from the submission of Medicaid [or Medicare] claims for *uncovered* off-label uses." *U.S. ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 52 (D. Mass. 2001) (emphasis added). To survive a motion to dismiss, it is not sufficient for Relators to merely allege off-label promotion; they must also plead specific uses that are not covered by federal healthcare programs. *See U.S. ex rel. Gohil v. Sanofi-Aventis U.S., Inc.*, No. 02-2964, 2015 WL 1456664, at \*11 (E.D. Pa. Mar.

30, 2015). Relators have failed to do so. For this reason, as well as the other reasons stated in Pfizer's prior briefing, the Court should dismiss Relators' amended complaint.

All of the purportedly off-label uses discussed in Relators' amended complaint are eligible for federal reimbursement. Two of these uses – empiric use and pediatric use – are supported by citations in the American Hospital Formulary Service Drug Information (“AHFS-DI”), one of the major drug compendia recognized under the Medicare and Medicaid statutes. (See Def.'s Response to Relators' Fourth Notice of Supplemental Authority at 2 n.1, ECF No. 88, Apr. 9, 2015.) For this reason, among others, these uses are “medically accepted” and therefore covered by federal healthcare programs. (See Def.'s Fourth Response at 2.) The very point of the FCA is to recover monies that the government should not have paid. Because empiric and pediatric use of Vfend are compendia-listed and the government would have paid for these uses despite the alleged underlying off-label promotion, these uses cannot be “false or fraudulent” as required under the FCA. *See Gohil*, 2015 WL 1456664, at \*11 (granting motion to dismiss based on major drug compendium that showed relator's allegations “only specify off-label uses which were medically accepted indications”).

Prior to filing their most recent Notice of Supplemental Authority, Relators argued the AHFS-DI does not support use of Vfend as empiric therapy or in pediatric patients. (Fifth Notice at 2-3, ECF No. 90, June 4, 2015.) In response, Pfizer explained that Relators have misrepresented the relevant compendium listings, obscuring their true meaning by cherry-picking passages and ignoring others that provide proper context. (Def.'s Fifth Response at 3-6, ECF No. 91, June 22, 2015.) For empiric use, Relators failed to mention that the AHFS-DI lists “Empiric Therapy in Febrile Neutropenic Patients” among the supported “Uses” of Vfend. (See Def.'s Fifth Response at 4-5.) For pediatric use, Relators highlighted a “caution” regarding

patients *younger* than 12 years of age, ignoring the fact that the compendium, like the approved labeling for Vfend, contains other language supporting the product's use in pediatric patients 12 years of age and older. (See Def.'s Fifth Response at 5-6.) Relators' arguments concerning the AHFS-DI are entirely unconvincing and the Court should disregard them.

Recognizing that Pfizer's arguments regarding the meaning of the compendium essentially gut Relators' case, Relators now make a flawed procedural argument that the meaning of the AHFS-DI is a question of fact better left for summary judgment. (Sixth Notice at 2-3.) Relators also argue that this case should proceed to discovery because empiric and pediatric use of Vfend are "medically unnecessary regardless of what the compendia state." (Sixth Notice at 3.) In making of these arguments, Relators cite *United States ex rel. Cestra v. Cephalon, Inc.*, No. 14-1842, 2015 WL 3498761 (E.D. Pa. June 3, 2015). For the reasons discussed in this memorandum, Relators' reliance on *Cephalon* is misplaced.

## ARGUMENT

### **I. THE COMPENDIA ENTRY AT ISSUE IN *CEPHALON* BEARS LITTLE RESEMBLANCE TO THOSE AT ISSUE IN THE PRESENT ACTION.**

According to Relators, *Cephalon* "establishes" that compendium references are "insufficient to dismiss Relator[s'] claims as a matter of law" because "Relators and Pfizer disagree on the import of the statements in the compendium and the complex inquiry would require fact discovery." (Sixth Notice at 3.) This statement is full of errors. As a factual matter, there is nothing "complex" about the meaning of the AHFS-DI with respect to empiric and pediatric use of Vfend. For the reasons discussed above, the compendium's meaning is obvious on its face. (See Def.'s Fifth Response at 3-6.) Moreover, as a legal matter, Relators have misrepresented the significance of *Cephalon*. To understand why, one must examine the facts of

that case, none of which appear in Relators' most recent Notice. (*See generally* Sixth Notice.) These facts are easily distinguishable from the present action.

The plaintiff in *Cephalon* alleged that the defendant promoted Treanda, an oncology medication, for various off-label uses, and this caused the submission of "false" claims to state Medicaid programs. *Cephalon*, 2015 WL 3498761, at \*8. In response, the defendant argued the relevant off-label uses are eligible for federal reimbursement because they are supported by the AHFS-DI. *Id.* The plaintiff disagreed, noting the compendium explicitly states that the safety and efficacy of these uses are "not fully established," which, in the plaintiff's view, means "not recommended." *Id.* Rather than announce a categorical rule that compendia-based arguments are "insufficient" to support a motion to dismiss (as Relators have suggested here), the *Cephalon* court actually said the following: "I am not inclined to resolve the question of whether Treanda was federally reimbursable for off-label uses based on drug compendia evidence at the motion to dismiss stage *where Relator has made detailed factual allegations in his second amended complaint that Treanda was not reimbursable.*" *Id.* at \*9 (emphasis added).

While the AHFS-DI says the off-label uses at issue in *Cephalon* are "not fully established," the compendium contains no similar language discouraging physicians from using Vfend as empiric therapy or in pediatric patients 12 years of age and older. (*See* Def.'s Fourth Response, Ex. A (attaching relevant AHFS-DI excerpts).) Moreover, Relators' amended complaint is devoid of "detailed factual allegations" explaining why the compendia would not support these uses. Instead, the amended complaint contains purely conclusory allegations on this point. (*See* Am. Compl. ¶ 38 ("At all times material to this First Amended Complaint, off-label uses of Vfend promoted by Pfizer are not eligible for reimbursement under Government Healthcare Programs because such off-label uses are neither listed in the labeling approved by

the FDA nor otherwise deemed safe and effective by any of the applicable drug compendia.”.) Courts in the Eastern District of Pennsylvania have dismissed FCA complaints containing similarly deficient allegations. *See Gohil*, 2015 WL 1456664, at \*11 (dismissing FCA complaint because plaintiff’s “conclusory” statement about the compendia “utterly fails to comport with the heightened pleading requirements of Rule 9(b)”). The amended complaint in this case deserves precisely the same treatment.

## **II. RELATORS HAVE FAILED TO IDENTIFY ANY SERIOUS SAFETY RISKS SPECIFICALLY RELATED TO EMPIRIC OR PEDIATRIC USE OF VFEND.**

Relators make one additional argument for why this Court ought to ignore the AHFS-DI when deciding the pending motion to dismiss. According to Relators, an FCA complaint can survive a motion dismiss, regardless of what the compendia say, if the complaint alleges that the relevant off-label uses are medically “risky.” (Sixth Notice at 3.) In support of this claim, Relators again cite *Cephalon*, but they present the case in a highly misleading manner.

In *Cephalon*, Judge Thomas N. O’Neill, Jr. notes that some “case law in the Eastern District of Pennsylvania implies that ‘it is sufficient for a relator to allege that an off-label use of a drug is medically risky in order to assume that the relator means the off-label use was medically unnecessary’ without reference to drug compendia.” *Cephalon*, 2015 WL 3498761, at \*10. Specifically, Judge O’Neill cites two district court cases, *United States ex rel. Bergman v. Abbott Labs.*, 995 F. Supp. 2d 357 (E.D. Pa. 2014) and *United States ex rel. Galmines v. Novartis Pharms. Corp.*, No. 06-3213, 2013 WL 2649704 (E.D. Pa. June 13, 2013). In these cases, the courts denied motions to dismiss where the plaintiffs alleged that the relevant off-label uses were associated with serious patient safety concerns. *See Bergman*, F. Supp. 2d at 360 (“Abbott also improperly promoted TriCor for use in combination with highly popular statin drugs even though TriCor was not approved for use in combination with statins by the FDA, and despite *specific*

**warnings** regarding combined use with statins contained in the FDA-mandated product labeling.”) (emphasis in original); *Galmines*, 2013 WL 2649704, at \*11 (“[T]he first amended complaint plausibly suggests that at least some of the claims submitted to government healthcare programs for Elidel prescriptions were not reimbursable, because it also alleges that these programs do not pay for drugs that are ‘not prescribed for a medically accepted indication,’ and that at least 1.2 million Elidel prescriptions were written off-label in a manner that put the health of the children receiving those prescriptions at risk.”).

Next, Judge O’Neill notes that other district courts in the Third Circuit have rejected the approach in *Bergman* and *Galmines*, focusing on the statutory compendia and not the “riskiness” of the alleged off-label uses. *Cephalon*, 2015 WL 3498761, at \*10 (citing *U.S. ex rel. Simpson v. Bayer Corp.*, No. 05-3895, 2013 WL 4710587, at \*11 (D.N.J. Aug. 30, 2013)). Contrary to the suggestion in Relators’ Sixth Notice, Judge O’Neill declined to choose between these approaches. *Id.* Rather, he merely said the following:

Without opining on whether there are different standards . . . I will note that here relator has alleged that the off-label use of Treanda was medically risky and that ***at least under the Court’s reasoning in Bergman*** that relator’s allegations would constitute a sufficient claim that the off-label use of Treanda for front-line treatment of iNHL is medically unnecessary regardless of any reference to the drug compendia.

*Id.* (citing allegations concerning “safety risks of off-label use of Treanda”) (emphasis added).

In their latest Notice, Relators distort the meaning of *Cephalon* by omitting the bolded language in the above quotation. (See Sixth Notice at 2-3 (“Therefore, because the relator ‘alleged that the off-label use of Treanda was medically risky . . . relator’s allegations would constitute a sufficient claim that the off-label use of Treanda for front-line treatment of iNHL is medically unnecessary regardless of any reference to the drug compendia.’”)). This alteration misleadingly suggests that *Cephalon* adopted *Bergman*. It did nothing of the sort.

Even assuming the *Bergman* standard applies, Relators are incorrect that they “have made detailed allegations that it is medically risky to use Vfend for the off-label uses” at issue here. (See Sixth Notice at 3.) Tellingly, Relators do not reference any paragraph in the amended complaint specifically alleging that empiric or pediatric uses of Vfend are themselves medically risky. (See Sixth Notice at 3.) No such allegation appears in their pleading. (See Am. Compl. ¶¶ 60-65 (empiric therapy), 125-133 (empiric therapy), 141-144 (pediatric use).) Instead, the potential safety risks mentioned in Relators’ complaint relate to other uses of Vfend, including use in neutropenic patients and patients with poor kidney function. (See Am. Compl. ¶¶ 6, 150-162.) In this way, the amended complaint is distinguishable from the pleadings at issue in *Cephalon*, *Bergman*, and *Galmines*, and Relators’ reliance on those cases is misplaced.<sup>1</sup>

### CONCLUSION

For these reasons, as well as those discussed in Pfizer’s previous briefing in support of its motion to dismiss, Pfizer respectfully asks this Court to dismiss Relators’ amended complaint, in its entirety, with prejudice.

Dated: November 13, 2015

Respectfully submitted,

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<sup>1</sup> At the conclusion of Relators’ latest Notice, they state, in conclusory fashion, that “*Cephalon* supports a kickback claims [sic] based upon facts that are very similar to those alleged by Relators.” (Sixth Notice at 3.) Pfizer’s arguments addressing Relators’ flawed kickback allegations can be found at pages 25-27 of the memorandum accompanying Pfizer’s pending motion to dismiss (ECF No. 42, Apr. 9, 2012).

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Dated: November 13, 2015

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